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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,088	09/12/2003	Andrew Vaillant	029849-0206	6597

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EXAMINER	
PENG, BO	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,088	VAILLANT ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 33-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/8/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed November 2, 2006. Claims 1-38 are pending. Claims 1, 2 and 33-38 are withdrawn as non-elected. Claims 3-32 are under the examination in the instant Office action. It is noted that Applicant elected the species of the oligonucleotide REP 2006, phosphorothioate linkage and 2'-O-methyl modification of the ribose moiety for examination.

2. The objection to the specification **is withdrawn** in view of the amendment to the specification.

3. Provisionally rejections of Claims 3-32 on the ground of nonstatutory obviousness-type double patenting, as being unpatentable over Claims 1-15 and 18-26 of co-pending Application No. 10/661,403; over Claims 22-51 of co-pending Application No. 10/661,402, over Claims 3-32 of co-pending Application No. 10/661,415, and over Claims 23-52 of co-pending Application No. 10/969,812, **are maintained**. Applicant wishes not to file a terminal disclaimer prematurely.

4. The followings are new ground of rejections. **This Office Action is Non-Final**.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The statement "...principally by a non-sequence complementary mode of action" in Claim 3 renders the claim indefinite because it is not clear what % of this mode of action is required to be "principally" and how this is determined. The specification does not provide a standard for ascertaining the requisite degree, which would allow one of ordinary skill in the art to be reasonably appraised of the scope of the invention. The statement "...said composition is approved for use in humans against HBV." in Claim 3 is also indefinite because it is not clear who said composition is approved by. This rejection affects all dependent claims.

8. Claim 16 recites the limitation "said formulation" in Claim 3 or 12. There is insufficient antecedent basis for this limitation in the claim.

9. Appropriate corrections are required.

Claim Rejections - 35 USC § 112, first paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 3-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detail chemical structure of the encompassed genus of undefined nucleotide fragment, proteins or polypeptides. Therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Lid.*, 18 USPQ2d 1016.

Applicant has disclosed a limited number of species; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

A description of a genus of protein sequences may be achieved by means of a recitation of a representative number of polypeptide sequences, defined by amino acid sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly&Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

12. Claims 3-32 are drawn to an antiviral pharmaceutical composition comprising a therapeutically effective amount of at least one pharmacologically acceptable, antiviral oligonucleotide at least 10 nucleotides in length, wherein said composition is approved for use in humans against HBV and the antiviral activity of said oligonucleotide occurs principally by a non-sequence complementary mode of action; and a pharmaceutically acceptable carrier.

13. Since the structural limitation to the claimed oligonucleotides is only minimal length, the

scope of Claims 3-32 encompasses all oligonucleotides that are more than 10 nucleotides in length. The possible variations are indefinite to such oligonucleotides longer than 10 nucleotides. The specification only provides description for 36 oligonucleotides, which do not constitute a representative number of species of such broad genus of all oligonucleotides longer than 10 nucleotides. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the oligonucleotides in the examples in the specification.

14. Since the specification lacks sufficient variety of species to reflect this highly variable genus of all antiviral oligonucleotide at least 10 nucleotides in length, there is no indication that Applicant was in possession of all antiviral oligonucleotides that are more than 10 nucleotides long as broadly claimed.

15. Claims 3-32 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

16. As discussed above, the scope of claims 3-32 encompasses indefinite oligonucleotides that are more than 10 nucleotides in length. The claims also recite: "the antiviral activity of said oligonucleotide occurs principally by a non-sequence complementary mode of action". However, since the specification has disclosed neither any structures of oligonucleotides whose antiviral activity "occurs principally by a non-sequence complementary mode of action", nor a correlation between the structures and "action mode" of the oligonucleotides, the skilled artisan cannot

envision the detailed structures and function of the genus of undefined oligonucleotides encompassed in the claims. To use/make instant pharmaceutical composition, one skilled in the art would have to make and test indefinite oligonucleotides that are more than 10 nucleotides in length to determine which also meet the functional limitation of antiviral activity, and the "action mode" limitation of "by a non-sequence complementary mode of action". Thus, it would take undue amount of experimentation to identify all antiviral oligonucleotides encompassed by the claims.

17. Furthermore, nature of the invention is directed to antiviral oligonucleotides for treating a viral infection. The nature of pharmaceutical arts is that it involves screening both in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities, providing clinical benefit. In the instant case, while Applicant has shown that some randomer oligonucleotides can inhibit DHBV in cell culture, the specification has not disclosed that such oligonucleotides can inhibit HBV in vivo. Those of skill in the art recognize that in vitro assays are generally useful to observe basic physiological and cellular phenomenon, such as a virus-cell interaction. However, the correlation of the physiological condition in vivo is generally lacking. Variables such as target accessibility and biological stability, half-life or rate of clearance from the blood are important parameters for oligonucleotide-based drugs in achieving their efficacy in vivo. However, neither prior art nor the instant specification has shown a correlation of anti-viral activities of oligonucleotides in vitro with their efficacy in vivo. One of skill in the art is unable to fully predict possible results of clinical benefit of claimed pharmaceutical composition of oligonucleotides only based on the results from cell culture assays.

18. Moreover, in order for the full breadth of the invention to be enabled, a skilled artisan

would have to develop a method to deliver claimed oligonucleotides to target cells in vivo. Although Applicant has suggested in the specification to delivery the oligonucleotide by using a delivery system, the state of the prior art has illustrated that the current delivery technology in the art is not sufficient to delivery oligonucleotide-based drugs to their targets in vivo (Opalinska, 2002). The specification has not provided any specific teachings regarding how to deliver oligonucleotides into target calls in vivo and how to maintain effective concentration in vivo at therapeutic levels to inhibiting multiplication of viral genomes during HBV replication. Because of the limitations of current gene delivery technology in the art and lack of guidance in the specification, it would require an undue quantity of necessary experimentation by one skilled in the art to develop a method to deliver claimed oligonucleotides in to target cells in vivo before using the instant pharmaceutical composition.

19. Since the scope of claims 3-32 clearly covers a genus of undefined antiviral oligonucleotides that are more than 10 nucleotides, in view of the empirical and unpredictable nature of development of antiviral oligonucleotides, and lack of guidance and working examples in the specification, it would require extensive experimentation for one of skill in the art to identify or make such the nucleic acids. Therefore, one of skill in the art cannot practice the claimed invention without undue experimentation.

20. In response to Applicant's arguments:

21. The Office acknowledges the declaration from Dr. Jean-Marc Juteau under 37 CFR 1.132 filed on November 2, 2006. The declaration presents some data showing that REP 2006 (40mer PS-randomer) and REP 2004 (20mer PS-randomer) and REP2031 can inhibit dHBV infection in

primary duck hepatocytes and cell lines. Dr. Jean-Marc Juteau concludes that the result "clearly proves that at least 3 different oligonucleotides of more than 10 nucleotides long as claimed in the present application are effective antiviral agents against HBV" (Paragraph 8, p. 12).

22. Dr. Jean-Marc Juteau' declaration has been fully considered and found unpersuasive. Dr. Jean-Marc Juteau' declaration is insufficient to overcome the rejection of Claims 3-32 based upon insufficiency of disclosure under 35 U.S.C. §112, first paragraph as set forth in the last Office action because the facts presented are not germane to the rejection at issue and the scope of showing is not commensurate in scope with the claims. The examples of the declaration are not representative of the whole scope of the claimed subject matter. The result showing "3 different oligonucleotides of more than 10 nucleotides long as claimed in the present application are effective antiviral agents HBV" is not sufficient to prove that Applicant was in possession of all antiviral oligonucleotides that are more than 10 nucleotides long as broadly claimed, and the instant specification has not taught one of skill how to make/use all other oligonucleotides longer than 10 nucleotides as a pharmaceutical composition.

23. Applicant also argues that co-pending application No.10/661,403 in vivo results demonstrate efficacy of the oligonucleotides of the present invention inhibit viral infection in eight different models (SIV, FLV, Influenza, RSV, Herpes virus 2, CMV, Ebola and Vaccinia virus). Therefore, it is believed that the efficacy of the oligonucleotides claimed in the application to inhibit viral infection of various families of virus is predicative of success for in vivo therapy following infection with HBV (Remarks, p. 5).

24. In response, Applicant's argument is not relevant because the disclosure of other applications cannot be incorporated into instant specification.

Claim Rejections - 35 USC § 102

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

26. Claims 3, 12, 14, 15, 17, 18, 21, 25, 26 and 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Pan (1995, PANS, 92, pp 11509-11513).

27. Claims 3, 12, 14, 15, 17, 18, 21, 25, 26 and 28-32 are directed to an antiviral pharmaceutical composition or a kit comprising a therapeutically effective amount of at least one pharmacologically acceptable, antiviral oligonucleotide at least 10 nucleotides in length, wherein said composition is approved for use in humans against HBV and the antiviral activity of said oligonucleotide occurs principally by a non-sequence complementary mode of action, wherein said at least one antiviral oligonucleotide comprises at least one antiviral randomer oligonucleotide, wherein said oligonucleotide is not complementary to any portion of the genomic sequence of HBV, wherein said oligonucleotide is at least 40 nucleotides in length, wherein each said oligonucleotide comprises at least one modification to its chemical structure, wherein each said oligonucleotide comprises at least one 2'-modification to the ribose moiety, wherein said

oligonucleotide is a concatemer consisting of two or more oligonucleotide sequences joined by a linker, wherein said oligonucleotide is linked or conjugated at one or more nucleotide residues, to a molecule modifying the characteristics of the oligonucleotide to obtain one or more characteristics selected from the group consisting of higher stability, lower serum interaction, higher cellular uptake, higher viral protein interaction, an improved ability to be formulated for delivery, a detectable signal, higher antiviral activity, better pharmacokinetic properties, specific tissue distribution, lower toxicity, wherein said oligonucleotide binds to one or more viral components, wherein at least a portion of the sequence of said oligonucleotide is derived from a viral genome, wherein the pharmaceutical composition, or kit comprises a mixture of at least two different antiviral oligonucleotides, wherein a plurality of said different oligonucleotides are at least 10 nucleotides in length, wherein a plurality of said different oligonucleotides are at least 40 nucleotides in length.

28 It is noted that Applicant elected the species of the oligonucleotide REP 2006, phosphorothioate linkage and 2'-O-methyl modification of the ribose moiety for examination. However, the oligonucleotide REP 2006 is not claimed in the instant claims. Therefore, the instant claims are examined to be not limited by the oligonucleotide REP 2006.

29. Pan teaches random RNA oligonucleotides having antiviral activity. Pan teaches construction of a DNA library containing about $5x10^{16}$ sequences using automated solid-state synthesis and then PCR amplification by randomizing a central 40-nt region (40N) of the 87-nt oligomer. Pan teaches that DNA library results in double-stranded random DNAs (about $5x10^{15}$ sequences). The random DNAs are then transcribed by T7 RNA

polymerase to generate a pool of multiple copies of about 10^{15} RNA sequences (random RNA pool) (Materials and Methods, pp 11509-11510). To increase the RNA stability against the nuclease digestion *in vivo*, Pan teaches that the random RNAs are modified by incorporating 2'-fluro-2-deoxycytidine and 2'-fluro-2-deoxyurine into the RNA chain (2'-F-RNAs). Pan teaches that the random RNAs and 2'-F-RNAs can neutralize RSV particles (Results, pp 11510-11512, and Figures 3 and 4).

30. Since Pan teaches that random DNA, RNA and modified RNA oligonucleotides are at least 10 or 40 nucleotide in length and "not complementary to any portion of the genomic sequence of HBV" (Claim 15), have antiviral activity, and their viral-neutralizing activity "occurs principally by a non-sequence complementary mode of action" (Claim 1), Pan's random oligonucleotides meet the structural and "action mode" limitations of the claims. Therefore, the instant Claims 3, 12, 14, 15, 17, 18, 21, 25, 26 and 28-32 are anticipated by Pan.

31. Please note that "...said composition is approved for use in humans against HBV." is not given a patentability weight because administrative issue of drug regulation is not relevant to the patentability of an invention.

32. Claims 3-13 and 16-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Davis (US 6,406,705).

33. Claims 3-13 and 16-24 and 26-32 are directed to an antiviral pharmaceutical composition or kit comprising a therapeutically effective amount of at least one pharmacologically acceptable, antiviral oligonucleotide at least 10 nucleotides in length, wherein said composition

is approved for use in humans against HBV and the antiviral activity of said oligonucleotide occurs principally by a non-sequence complementary mode of action; and a pharmaceutically acceptable carrier, wherein the antiviral pharmaceutical composition is adapted for delivery enterally, topically, by oral ingestion, by injection, by inhalation, wherein said composition further comprises a liposomal formulation, wherein said composition further comprises at least one other antiviral drug in combination, wherein said formulation has an IC_{50} for HBV of 0.10 μM or less, wherein said oligonucleotide is at least 40 nucleotides in length, wherein each said oligonucleotide comprises at least one modification to its chemical structure, wherein each said oligonucleotide comprises at least one phosphorothioated linkage and is in a formulation comprising a delivery system, wherein each said oligonucleotide comprises at least one 2'-modification to the ribose moiety, wherein each said oligonucleotide comprises at least one methylphosphonate linkage, wherein each said oligonucleotide comprises at least one phosphorodithioated linkage, wherein said oligonucleotide is a concatemer consisting of two or more oligonucleotide sequences joined by a linker, wherein said oligonucleotide is linked or conjugated at one or more nucleotide residues, to a molecule modifying the characteristics of the oligonucleotide to obtain one or more characteristics selected from the group consisting of higher stability, lower serum interaction, higher cellular uptake, higher viral protein interaction, an improved ability to be formulated for delivery, a detectable signal, higher antiviral activity, better pharmacokinetic properties, specific tissue distribution, lower toxicity, wherein said oligonucleotide is double stranded, wherein said oligonucleotide binds to one or more viral components, wherein at least a portion of the sequence of said oligonucleotide is derived from a viral genome, wherein the pharmaceutical composition, or kit comprises a mixture of at least two

different antiviral oligonucleotides, wherein a plurality of said different oligonucleotides are at least 10 nucleotides in length, wherein a plurality of said different oligonucleotides are at least 40 nucleotides in length.

34. Davis teaches that immunostimulatory oligonucleotides having at least one unmethylated CpG dinucleotide (CpG ODN) can be used for induction of cellular immunity against HBV (Abstract, Column 35, Examples 1-6). Davis teaches that CpG ODN includes at least the following formula: 5'-$X_1X_2CGX_3X_4$-3' and 5'-$N_1X_1X_2CGX_3X_4N_2$-3'. The CpG ODN may be any size, preferably 8 to 100 nucleotides, or 8 to 40 nucleotides in length (Lines 1-32, Column 4, also see Table 1). The CpG ODN can be double-stranded or single-stranded (Line 50-55, Column 10 and Column 11). Davis teaches that chemical modification of the oligonucleotide backbone provides enhanced immunogenicity of the CpG oligonucleotides *in vivo* (Lines 52-62, Column 12). CpG ODN constructs, including at least two phosphorothioate linkages at the 5' end of the oligonucleotide in multiple phosphorothioate linkages at the 3' end, preferably 5, provides maximal activity and protected the oligonucleotide from degradation by intracellular exo- and endo-nucleases. Other modified oligonucleotides include phosphodiester-modified oligonucleotides, combinations of phosphodiester and phosphorothioate oligonucleotides, methylphosphonates, methylphosphorothioates, phosphorodithioates, and combinations thereof. Davis teaches that the pharmaceutical compositions of CpG ODN can be administered by intramuscular, intradermal injection, intranasal application, inhalation, topically, intravenously, or orally. CpG ODN can be formulated in liposomes or other drug delivery systems (Line 61, Column 31 to Line 15, Column 32). Davis teaches that the use of CpG ODN as an adjuvant alone or in combination with other adjuvants (Lines 8-13, Column 34).

35. Since Davis teaches that CpG ODN at least 10 nucleotides in length can be used against HBV, and its immunostimulatory activity works "principally by non-sequence complementary mode of action", Davis CpG ODN meets the limitation of Claims 3-13 and 16-24 and 26-32. Thus. the instant Claims 3-13 and 16-24 and 26-32 are anticipated by Davis.

Remarks

36. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BP

Bo Peng, Ph.D.
January 18, 2007

Bruce Campell

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